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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/577,974	05/30/2007	Barbara Ensoli	50318/012001	3028	
21559	7590	07/24/2008	EXAMINER		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110		KINSEY WHITE, NICOLE ERIN			
		ART UNIT		PAPER NUMBER	
		1648			
		NOTIFICATION DATE		DELIVERY MODE	
		07/24/2008		ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

[patentadministrator@clarkelbing.com](mailto:patentadministrator@clarkelbing.com)

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/577,974	ENSOLI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	NICOLE KINSEY WHITE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 April 2008.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-13 is/are pending in the application.  
 4a) Of the above claim(s) 10, 12 and 13 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-9 and 11 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/27/2006</u> .   | 6) <input type="checkbox"/> Other: _____ .                        |

### **DETAILED ACTION**

Applicants' election with traverse of Group I (claims 1-9 and 11) in the reply filed on April 28, 2008 is acknowledged. The traversal is on the ground that Laus et al. does not teach a disease associated antigen adsorbed to the surface of the microparticle. This argument is not found persuasive.

Laus et al. discloses a microparticle comprising: (a) a core which comprises a water insoluble polymer or copolymer, and (b) a shell which comprises a hydrophilic polymer or copolymer and functional groups which are ionic or ionisable; said microparticle having BSA adsorbed at the external surface (see the entire document, especially the results and discussion). Laus et al. does not teach a disease associated antigen. However, Laus et al. teaches that the surface of the microparticles is protein friendly (i.e., proteins are easily immobilized on the surface) and that the microspheres can be used for immobilizing high amounts of protein for protein delivery systems where the protein is protected from degradation (see page 283).

Therefore, it would have been obvious to one of ordinary skill in the art to substitute any other protein, including disease-associated antigens, on the surface of the microparticle of Laus et al. and the results would have been predictable (i.e., a microparticle with protein adsorbed on the surface).

The requirement is still deemed proper and is therefore made FINAL.

***Specification***

The disclosure is objected to because of the following informalities: Pages 41 and 56 of the specification recite sequences without the appropriate sequence identifiers. Appropriate correction is required.

***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on September 27, 2006 was filed before the mailing date of the first office action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. However, with regard to DE 3048883, DE 10118852 and EP 0240424, only the English equivalents of DE 3048883 and DE 10118852 and the English abstract of EP 0240424 have been considered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 contains the trademark/trade name Eudragit L100-55. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35

U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a copolymer of methlyacrylic acid and ethyl acrylate and, accordingly, the identification/description is indefinite.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laus et al. (Journal of Controlled Release, 2001, 72:225-309) in view of Betti et al. (Vaccine, 2001, 19:2308-3419), Caputo et al. (Vaccine, 2003, 21:1103-1111), Caselli et al. (Journal of Immunology, 1999, 162:5631-5638) and O'Hagan et al. (WO 98/033487).

The claims are directed to a microparticle comprising:

(a) a core which comprises a water insoluble polymer or copolymer, and  
(b) a shell which comprises a hydrophilic polymer or copolymer and functional groups which are ionic or ionisable; said microparticle having a disease-associated antigen adsorbed at the external surface.

Laus et al. discloses a microparticle comprising: (a) a core which comprises a water insoluble polymer or copolymer, and (b) a shell which comprises a hydrophilic polymer or copolymer and functional groups which are ionic or ionisable; said microparticle having BSA adsorbed at the external surface (see the entire document, especially the results and discussion). The microspheres are made of polystyrene or polymethylmethacrylate with hemisuccinated polyvinylalcohol or Eudragit L100/55 as the hydrophilic copolymer. The microspheres range in size from 0.5 to 20  $\mu\text{m}$ .

Laus et al. does not teach a disease associated antigen adsorbed to the microparticles. However, Laus et al. teaches that the surface of the microparticles is protein friendly (i.e., proteins are easily immobilized on the surface) and that the microspheres can be used for immobilizing high amounts of protein for protein delivery systems where the protein is protected from degradation (see page 283). In addition, Betti et al., Caputo et al. (2003) and Caselli et al. teach the use of HIV Tat as a vaccine

candidate and the use of copolymers to deliver HIV Tat DNA to a subject. Furthermore, it is well known in the art to use microparticles with adsorbed HIV antigens as vaccines (see, for example, O'Hagan et al. O'Hagan et al. used microparticles to deliver HIV p24 gag and to induce cytotoxic T-lymphocyte activity, see page 14, line 10 to page 15, line 13, and Examples 9 and 10 of O'Hagan et al.).

Therefore, it would have been obvious to one of ordinary skill in the art to substitute any other protein, including disease-associated antigens, on the surface of the microparticle of Laus et al. and the results would have been predictable (i.e., a microparticle with protein adsorbed on the surface). Further, in view of Laus et al.'s suggestion to use the microspheres as protein delivery vehicles and the teachings of O'Hagan et al. to use protein coated microparticles to induce an immune response, it would have been obvious for one of ordinary skill in the art to use the protein coated microspheres of Laus et al. to generate an immune response in a subject.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 and 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 10-15 and 17 of copending Application No. 10/577,973. Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept.

The subgenus claims of copending application 10/577,973 anticipate the instant genus claims, and a patent to the instant genus claims would, necessarily, extend the rights of the a patent granted to the sub-genus claims should both applications issue as a patent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE KINSEY WHITE whose telephone number is (571)272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicole Kinsey White, PhD/  
Examiner, Art Unit 1648

/Stacy B Chen/  
Primary Examiner, Art Unit 1648